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(71) Applicant *(for all designated States except US)*: **INSTRUMENTARIUM OYJ** [FI/FI]; Datex-Ohmeda Division, Teollisuuskatu 27, FIN-00510 Helsinki (FI).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **RANTALA, Börje** [FI/FI]; Kivimäentie 56 B, FIN-00670 Helsinki (FI). **TOIMELA, Kari** [FI/FI]; Fleminginkatu 23 B 31, FIN-00500 Helsinki (FI).

(74) Agent: PATENT AGENCY COMPATENT LTD.; Pitkänsillanranta 3B, FIN-00530 Helsinki (FI).

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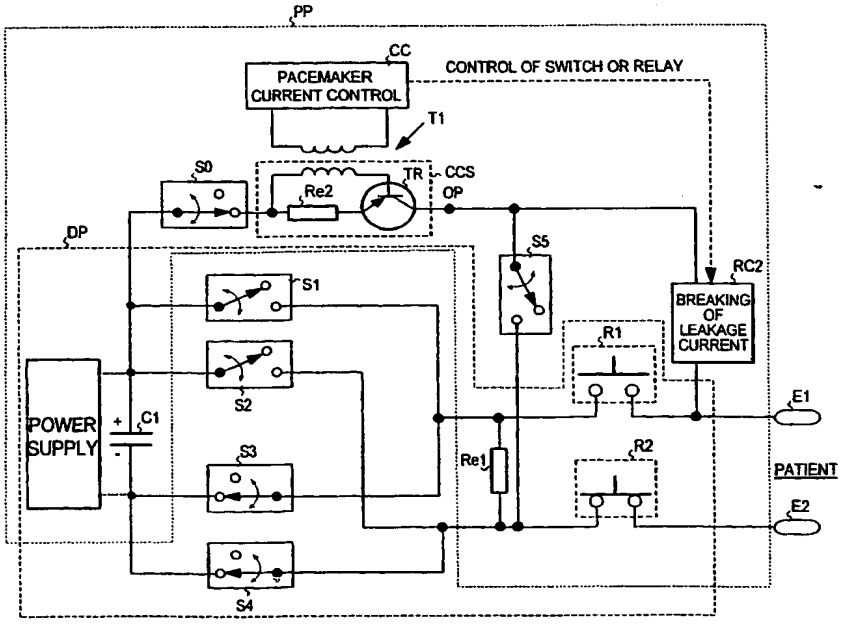
(54) Title: COMBINED DEFIBRILLATOR AND PACEMAKER



(57) Abstract: The invention relates to a combined defibrillator and pacemaker. To enable a smaller, lighter and more cost-effective structure than hitherto, the defibrillator part and pacemaker part use the same high-voltage capacitor (C1) as the storage of pulse energy, from which capacitor a current path has been established through at least one breaking element (RC2) for patient leakage current, preferably a second capacitor, to a patient electrode (E1) for supplying a pacemaking pulse train via said current path to said patient electrode.

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Combined defibrillator and pacemaker

Field of the Invention

The invention relates generally to defibrillation and to implementation of pacemaking. In particular, the invention relates to the integration of defibrillation and pacemaking functions into the same device in such a way that both defibrillation and pacemaking can be carried out by the apparatus.

Background of the Invention

Ventricular fibrillation is a chaotic heart pace on account of which the heart does not pump blood efficiently enough. This will probably result in cardiac arrest. The best way to prevent cardiac arrest is defibrillation carried out early enough. Defibrillation denotes applying a strong current pulse through the heart to terminate fibrillation. Defibrillators again are apparatus by means of which the current pulse is applied to the patient. There are both external and internal defibrillators, and various pulse forms are used therein to eliminate fibrillation.

Until recent years, the pulse form employed in external defibrillators has been the monophasic pulse, which means that the current pulse applied to the patient maintains its direction during the entire duration of the pulse. In monophasic defibrillators, the maximum energy applied to the patient is normally approximately 360 J. (Assuming that the impedance of the patient is about 50 Ω. Generally, the requisite energy is proportional to the inverse of the impedance.) In the 1990's, also the biphasic pulse form has been introduced in external defibrillators. This pulse form has been applied already for years in internal defibrillation (i.e., applied directly to the cardiac surface). The biphasic pulse form has the advantage that to achieve successful defibrillation, the pulse energy need not be as great as with the monophasic pulse (in practice, the energy of the biphasic pulse is in the order of 150...250 J). On account of this, smaller patient currents, smaller component sizes and lesser disadvantage to the patient are achieved.

Figure 1 illustrates a typical biphasic defibrillation pulse. A biphasic pulse comprises two parts (phases) that are denoted with references A and B in the figure. In the latter part (B), the direction of the current is reverse to that of the first part (A). The length of the entire pulse is typically in the order of 10

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ms. One explanation for the effectiveness of the biphasic defibrillation pulse is the fact that the latter phase strives to restore the voltage accumulated across the myocardial cell membranes back to its initial state and thereby to prevent reoccurrence of fibrillation. This mechanism is described in detail for example in the article Kroll, MW: *A Minimal Model of the Single Capacitor Biphasic Defibrillation Waveform*, PACE, November 1994, Part I, pp. 1782-1792, wherefrom the interested reader can gain more background information on the topic. Since, however, the fibrillation and defibrillation mechanisms are not essential to the actual invention or the understanding thereof, they will not be described in detail in this context.

Most defibrillators also incorporate a synchronizing function enabling well-timed application of a current pulse in relation to the patient heart rate (electrocardiogram). This synchronizing feature is necessary in the treatment of other forms of cardiac arrhythmias than ventricular fibrillation, since a pulse applied at an incorrect locus of the electrocardiogram may result in ventricular fibrillation. In such cases, synchronized cardioversion is concerned.

The purpose of an external temporary pacemaker is, for its part, to assist the resuscitation of patients suffering from arrhythmia. In external pacemaking, a regular electrical pulse train is applied to the patient via electrodes attached to the patient's chest. By this means, the patient's heart can be stimulated synchronously and an effective pumping rhythm is established. Pacemaking differs from defibrillation in character, since the energy of the synchronizing pulse is considerably lower than that of the defibrillation pulse, and the pacemaking function is a relatively long-term operation compared to defibrillation. The duration of the pacemaking function can vary from several minutes up to hours.

A modern defibrillator usually also integrates an external temporary pacemaker. The current implementations are typically as shown in Figure 2, i.e., they have a dedicated circuit for the defibrillation function (10) and the pacemaking function (20). These circuits usually employ common electrodes (E1, E2) that are attached to the patient. The control unit CU of the apparatus is employed for selecting whether the apparatus is used in the defibrillation mode or in the pacemaking mode, and consequently one of the circuits is switched to the electrodes by means of switches (SW1...SW4). The implementation of the defibrillation and pacemaking functions with separate

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circuits is due to the fact that said functions are difficult to combine, as they are electrically very different and one may not interfere with the other so as to impair the result of the operation to be performed or to cause any other disadvantage to the patient. For example in the pacemaking function (which by nature is of long duration), it is essential that the patient electrodes are not polarized and thereby do not impair the measurement of the electrocardiogram. (The electrocardiogram is measured from the same electrodes that are used for defibrillation or pacemaking.) Polarization may also cause electrolytic irritation at the electrode-skin interface.

On account of structural parallelity, the combination of defibrillator and pacemaker is quite complex and also costly to implement. The clear distinctiveness of the operations also adversely affects the size and weight of the apparatus.

Summary of the Invention

The objective of the present invention is to eliminate the drawbacks described above and to provide a combination of defibrillator and pacemaker that is compact in structure and more cost-effective than hitherto.

This objective is achieved with the solution defined in the independent claims.

The basic idea of the invention is to use the capacitor employed as the energy storage for the defibrillation pulse also as an energy storage for pacemaking pulses, and to switch the pacemaking pulses to the patient through at least one disconnecting or breaking element for patient leakage current, preferably through at least one other capacitor. Patient leakage current refers to a current leaking from the defibrillator/pacemaking apparatus through the patient to the ground or from the patient through the apparatus to the ground, said current being generated by an unintentional voltage external to the patient. The disconnecting or breaking element prevents the passage of such a current, or at least the DC component thereof, to the patient.

On account of the solution in accordance with the invention, patient leakage currents of e.g. the pacemaking part can be effectively eliminated. Thanks to the compact structure, the apparatus can also be made lighter than heretofore. Reducing the size and weight is of advantage particularly when the apparatus is being used by perambulatory paramedics, such as ambulance

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crew.

In a preferred embodiment of the invention, both the defibrillator and the pacemaker are biphasic, and furthermore, during the latter phase of the pacemaking pulse the charge accumulated in the capacitance of said at least one other capacitor or the capacitance of a patient electrode during the first phase is discharged.

Brief Description of the Drawings

The invention and its preferred embodiments will be described in greater detail in the following with reference to Figures 3...5 in examples in accordance with the accompanying drawings, in which

Figure 1 illustrates a typical pulse form applied by a defibrillator to electrodes attached to a patient,

Figure 2 shows a typical prior art defibrillator into which a pacemaking function is incorporated,

Figure 3 depicts a combination of defibrillator and pacemaker in accordance with the invention in the initial situation of the pacemaking operation,

Figure 4a shows an apparatus in accordance with Figure 3 during the first phase of the defibrillation pulse,

Figure 4b shows the apparatus of Figure 4a during the latter phase of the defibrillation pulse, and

Figure 5 depicts the pulse train to be applied to the patient in the pacemaking function of the apparatus depicted in Figures 4a and 4b.

Detailed Description of the Invention

Figure 3 illustrates the combination of defibrillator and pacemaker in accordance with the invention in the initial state of the pacemaking function. In the connection shown in the figure, the biphasic defibrillator part is implemented using an H-bridge connection known per se, employing one or more high-voltage capacitors C1. The energy of the defibrillation pulse is charged in this high-voltage capacitor whose plus terminal is connected through switch S1 and relay R2 to a first patient electrode E1 and through switch S2 and relay R2 to a second patient electrode E2. The minus terminal of the capacitor again is connected through switch S3 and relay R1 to the first patient electrode E1 and

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through switch S4 and relay R2 to the second patient electrode E2. The patient electrodes (which are attached to the patient) are thus disconnected from the apparatus by means of relays (or other corresponding patient disconnecting means). The relay terminals facing away from the patient (which in this connection are called the first relay terminals) are interconnected with a resistance Re1, the task of which is to effectively short-circuit the leakage currents from switches S1...S4 when the switches are in non-conductive state, so that the voltage across relays R1 and R2 is always considerably less than 500 V. The size of the resistance is in the order of 10 $k\Omega$...1 $M\Omega$.

The plus terminal of the defibrillation capacitor is further connected through switch S0 to a constant-current power source CCS, whose output OP is again connected through a breaking or disconnecting element RC2 for patient leakage current to the first patient electrode E1 (i.e., to the terminal of relay R1 facing the electrode) and through switch S5 to the first terminal of relay R2. The disconnecting element is preferably a capacitor, but it may also be a switch or a relay. The constant-current power source is controlled by means of a control circuit CC by adjusting the throughgoing resistance of transistor TR (the resistance between the emitter and the collector) through transformer T1, and thereby the current passing through the transistor. The constant-current power source and the control thereof are implemented in a known manner, and therefore will not be described in greater detail in this context. If the disconnecting element is a switch or a relay, it is brought to conductive state by means of the control circuit for the duration of the pacing pulse. If the disconnecting element is a capacitor, no control is needed.

The apparatus shown in Figure 3 naturally also includes a power source by means of which the capacitor C1 is charged to the desired voltage and control means by means of which the operation of the switches is controlled. For simplicity, the power source is only depicted in Figure 3 and the control means are not shown at all. In Figure 3, the defibrillator part of the apparatus is denoted with a broken line indicated with reference DP and the pacemaking part with a broken line indicated with reference PP.

In practice, switches S1...S5 can be implemented for example with IGBT transistors, SCR thyristors or combinations of these.

In the following, the operation of the defibrillator/pacemaker in accordance with the invention is described in detail with reference to Figures 4a, 4b

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and 5. In Figures 4a and 4b, the disconnecting element RC2 for leakage current is depicted as a capacitor.

When the apparatus is in defibrillation mode, switches S0 and S5 are turned off. In the defibrillation operation, capacitor C1 is first charged to the required high voltage (typically in the order of 2.5 kV) using a suitable power source, such as a switched-mode power supply. Relays R1 and R2 are turned on immediately before the application of the current pulse, that is, the patient is connected to the defibrillator part immediately prior to the application of the current pulse. At other times, the relays are turned off to prevent any patient leakage current. To apply the first phase of a biphasic current pulse to the patient, switches S1 and S4 are first turned on while switches S2 and S3 are turned off. During the first phase, the switches and relays are thus in the position shown in Figure 4a. When the second phase starts, switches S1 and S4 are turned off and switches S2 and S3 are turned on. During the second phase, the switches and relays are thus in the position shown in Figure 4b, and thus the current passes through the patient in the reverse direction as compared to the first phase. Immediately after the application of the defibrillation pulse, relays R1 and R2 are turned off to avoid any leakage current to the patient.

Defibrillators must also incorporate an internal discharge for the high-voltage capacitor. The constant-current power source CCS of the pacemaker can be used for this purpose in such a way that no energy is conducted to the patient. This is effected in such a way that the relays are turned off and only switches S0, S5 and S4 are conductive. By adjusting the current in the constant-current power source CCS to be suitable, capacitor C1 can be discharged in a controlled manner.

For external pacemaking, the switches are initially in the position shown in Figure 3, that is, switches S0 and S4 are turned on, switches S1, S2 and S5 are turned off, relay R1 is turned off and relay R2 is turned on. In this case, the high-voltage capacitor C1 is charged to pacemaking voltage, which is a voltage considerably lower than the defibrillation voltage, typically in the order of 250 V. The voltage is generated either by charging the capacitor from the power source or discharging the defibrillation voltage, depending on whether the apparatus has been used for defibrillation previously.

In pacemaking, a continuous pulse train in accordance with Figure 5

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is supplied to the electrodes, in which pulse train one pacemaking pulse comprises two phases similarly as the defibrillation pulse. These phases are denoted with references A and B in the figure similarly as in Figure 1. As stated previously, in pacemaking the pulse frequency is typically 40...180 pulses per minute, and therefore the duration T of the phase typically varies in the range 0.33 s...1.5 s. The length of one biphasic pacemaking pulse is dependent on the patient but is typically between 10 and 40 ms. The first part (A) of the biphasic pacemaking pulse is applied to the patient through switch S0, constant-current power source CCS and disconnecting element RC2 for patient leakage current. If the disconnecting element is a capacitor, the voltage across it is 0 V in the initial state but rises linearly (constant current). The second part (B) of the pacemaking pulse is generated by turning switch S5 on, as a result of which capacitor RC2 is discharged through switch S5. Therefore, during the second phase (B) the current passing through the patient is reverse to that of the first phase, thus rendering the pacemaker is biphasic, like the defibrillator. If it is desired to restrict the current in the second phase, a resistance can be connected in series with switch S5. The above biphasic operation is continued at the desired frequency, the pulse train supplied to the electrodes (patient) being in accordance with Figure 5. The first part of the pacemaking pulse is preferably a constant-current pulse and the second part discharges the charge accumulated in capacitor RC2 or the capacitance of the electrode during the first phase. Capacitor RC2 will eliminate the DC component of a patient leakage current when the electrodes attached to the patient are in place for a longer period and the pacemaker is not turned on.

As stated previously, an alternative way to prevent any patient leakage current from the pacemaking part is to use as the disconnecting or breaking element RC2 a relay or a switch that is only turned on for the duration of the pacemaking pulse under control of the control circuit. In that case, the pacemaking pulse is monophasic and the above stated linear voltage rise across the disconnecting element does not occur. By means of a switch and a relay, both the AC and the DC component of the patient leakage current can be cut off. However, a capacitor has the advantage that it does not need any control and it enables, in the simple manner described above, a biphasic pacemaker preventing the above-stated polarization of electrodes.

Even though the invention has been described in the above with

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reference to examples in accordance with the accompanying drawings, it is obvious that the invention is not to be so restricted, but it can be modified within the scope of the inventive idea disclosed in the appended claims. For example, both parts need not necessarily be biphasic, although biphasic implementations afford the advantages described at the beginning. Various monitoring means can also be incorporated into the apparatus for monitoring the condition of the patient.

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Claims:

1. An arrangement for implementing a combined defibrillator and pacemaking apparatus, said arrangement comprising

- a defibrillator part (DP) for generating a defibrillation pulse, said defibrillator part comprising first energy storing means (C1) for storing the energy of the defibrillation pulse, and

- a pacemaking part (PP) for generating a pacemaking pulse train, said pacemaking part comprising second energy storing means for storing the energy of the pacemaking pulse, and

- patient electrodes (E1, E2), connectable to the defibrillator part for receiving the defibrillation pulse and to the pacemaking part for receiving the pacemaking pulse train,

characterized in that

- the first and second energy storing means are implemented with the same high-voltage capacitor (C1) from which a current path has been established through at least one breaking element (RC2) for patient leakage current to a patient electrode for supplying the pacemaking pulse train via said current path to said patient electrode.

2. An arrangement as claimed in Claim 1, characterized in that a capacitor is employed as the breaking element for patient leakage current.

3. An arrangement as claimed in Claim 2, having two patient electrodes each of which can be disconnected by means of their dedicated disconnecting means (R1, R2) from the defibrillator part, characterized in that said at least one capacitor is connected between the first patient electrode (E1) and the disconnecting means (R1) connected thereto.

4. An arrangement as claimed in Claim 3, characterized in that the disconnecting means (R1) connected to the first patient electrode (E1) are switched to be non-conductive and the disconnecting means connected to the second patient electrode (E2) are switched to be conductive for the duration of the pacemaking pulse train, and hence during the pacemaking pulse the current passes through said at least one capacitor, the patient, and the disconnecting means switched to be conductive.

5. An arrangement as claimed in Claim 2, characterized in

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that the pacemaking part comprises current reversing means (S5) for reversing the direction of the current passing through said at least one capacitor.

6. An arrangement as claimed in Claim 2, characterized in that the pacemaking pulse is supplied to the patient electrodes in biphasic form in such a way that the current through said at least one capacitor passes in reverse directions in the different phases.

7. An arrangement as claimed in Claim 6, characterized in that the first phase consists of a constant-current pulse.

8. An arrangement as claimed in Claim 7, characterized in that the second phase discharges the charge accumulated in said at least one capacitor during the first phase.

9. An arrangement as claimed in Claim 4, characterized in that the first disconnecting means (R1) is connected to the first terminal of the high-voltage capacitor through a first switch (S1) and to the second terminal of the high-voltage capacitor through a second switch (S3), and that the second disconnecting means (R2) is connected to the first terminal of the high-voltage capacitor through a third switch (S2) and to the second terminal of the high-voltage capacitor through a fourth switch (S4).

10. An arrangement as claimed in Claim 1, characterized in that a relay or a switch that is brought to conductive state during the pacemaking pulse is employed as the breaking element for patient leakage current.

11. An arrangement as claimed in Claim 9, characterized in that the first, second, third and fourth switch and the current reversing means are implemented with IGBT transistors, SCR thyristors or combinations thereof.

12. An arrangement for implementing a combined defibrillator and pacemaking apparatus, said arrangement comprising

- first means (PP) for generating a pacemaking pulse train,
- second means (DP) for generating a defibrillation pulse, said second means comprising a high-voltage capacitor (C1) for storing the energy of the defibrillation pulse,

characterized in that

- the high-voltage capacitor is also employed for storing the energy of the pacemaking pulses.

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13. An arrangement as claimed in Claim 12, characterized in that the pacemaking pulse train is applied to the patient through at least one breaking element (RC2) for patient leakage current.

14. An arrangement as claimed in Claim 12, characterized in that an other capacitor (C2) is employed as the breaking element.

15. An arrangement for implementing a combined defibrillator and pacemaking apparatus, said arrangement comprising

- first means (PP) for generating a pacemaking pulse train,
- second means (DP) for generating a defibrillation pulse,

characterized in that

- the pacemaking pulse train is applied to the patient through at least one breaking element (RC2) for patient leakage current.

16. An arrangement as claimed in Claim 15, characterized in that a capacitor (C2) is used as the breaking element for patient leakage current.

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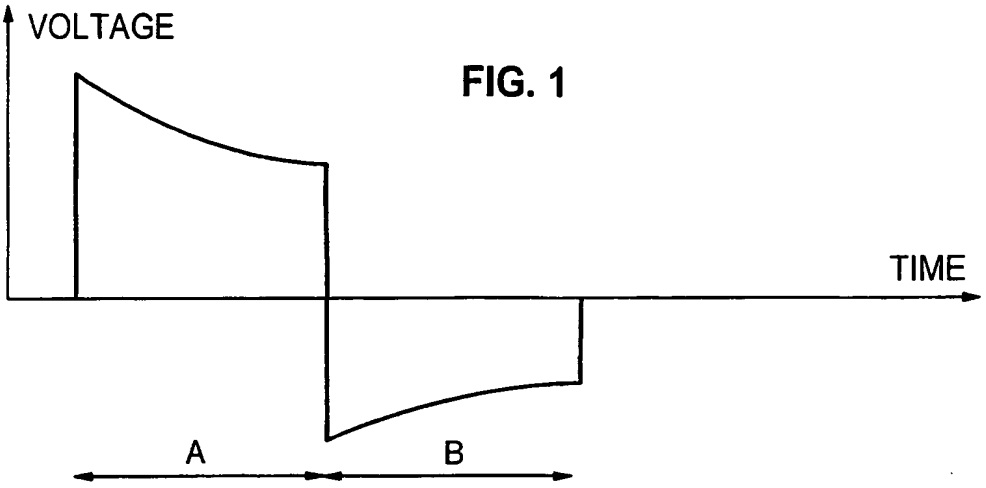

FIG. 1

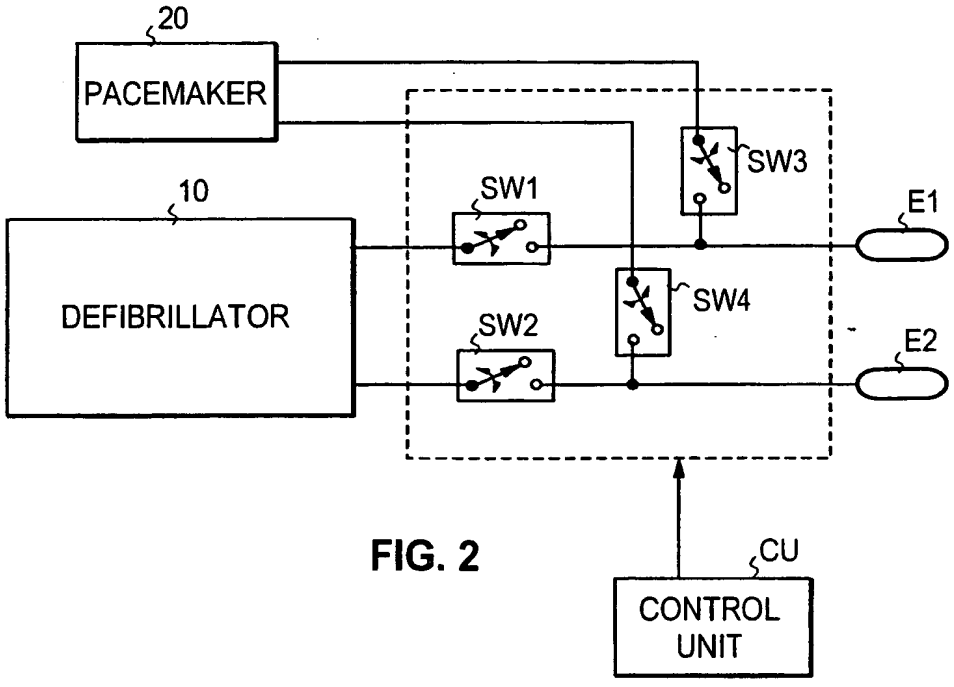

FIG. 2

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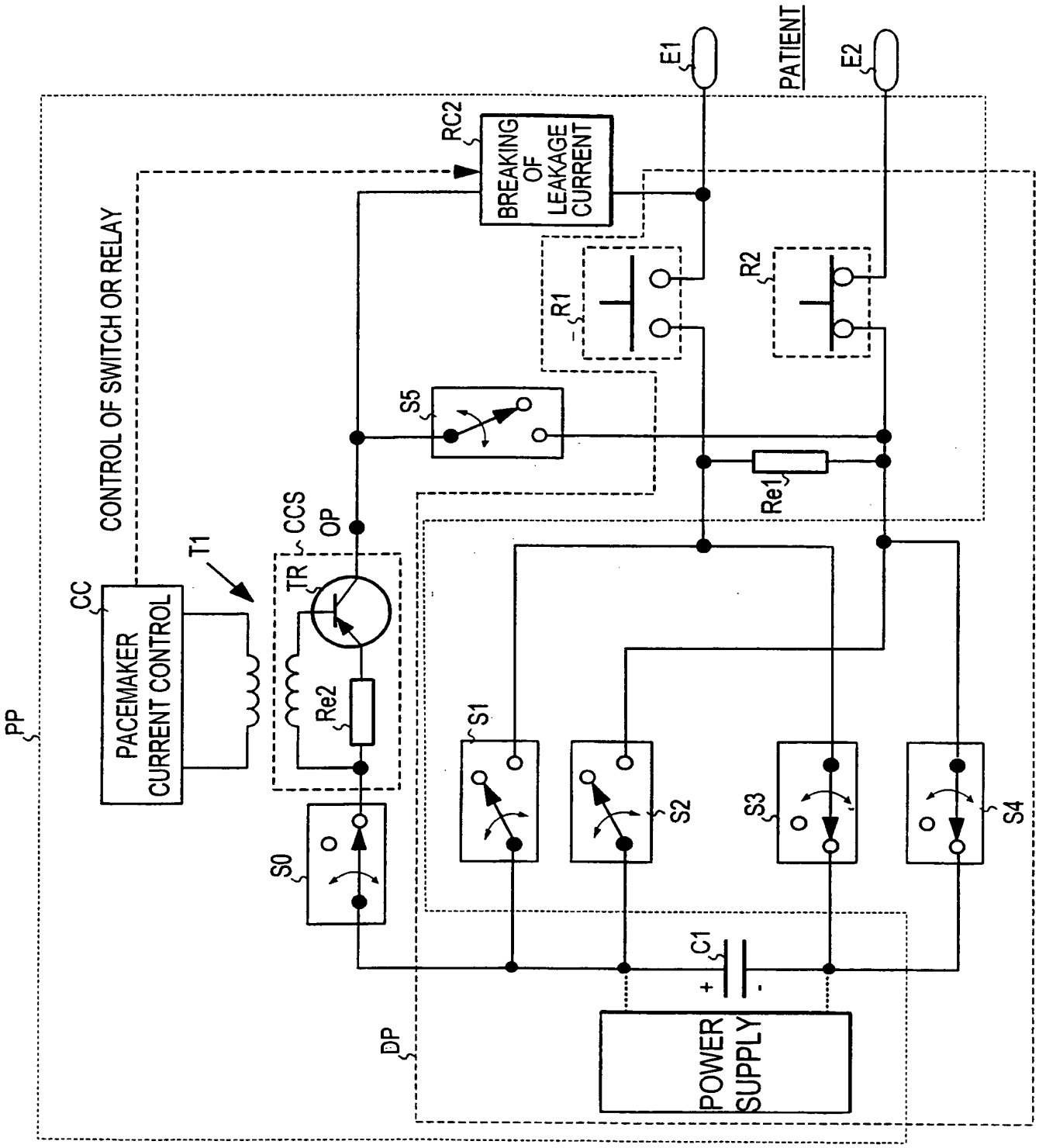

FIG. 3

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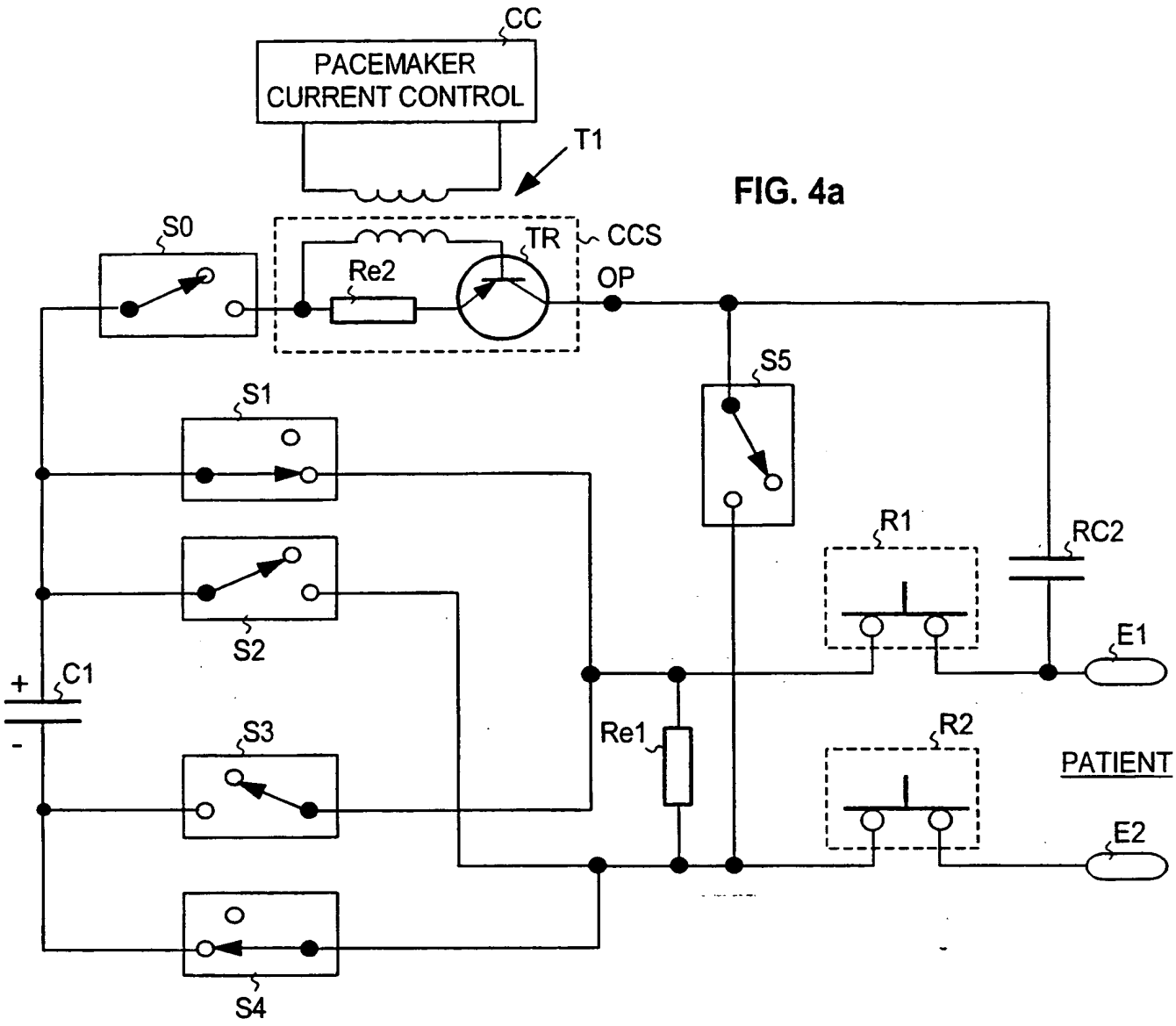

FIG. 4a

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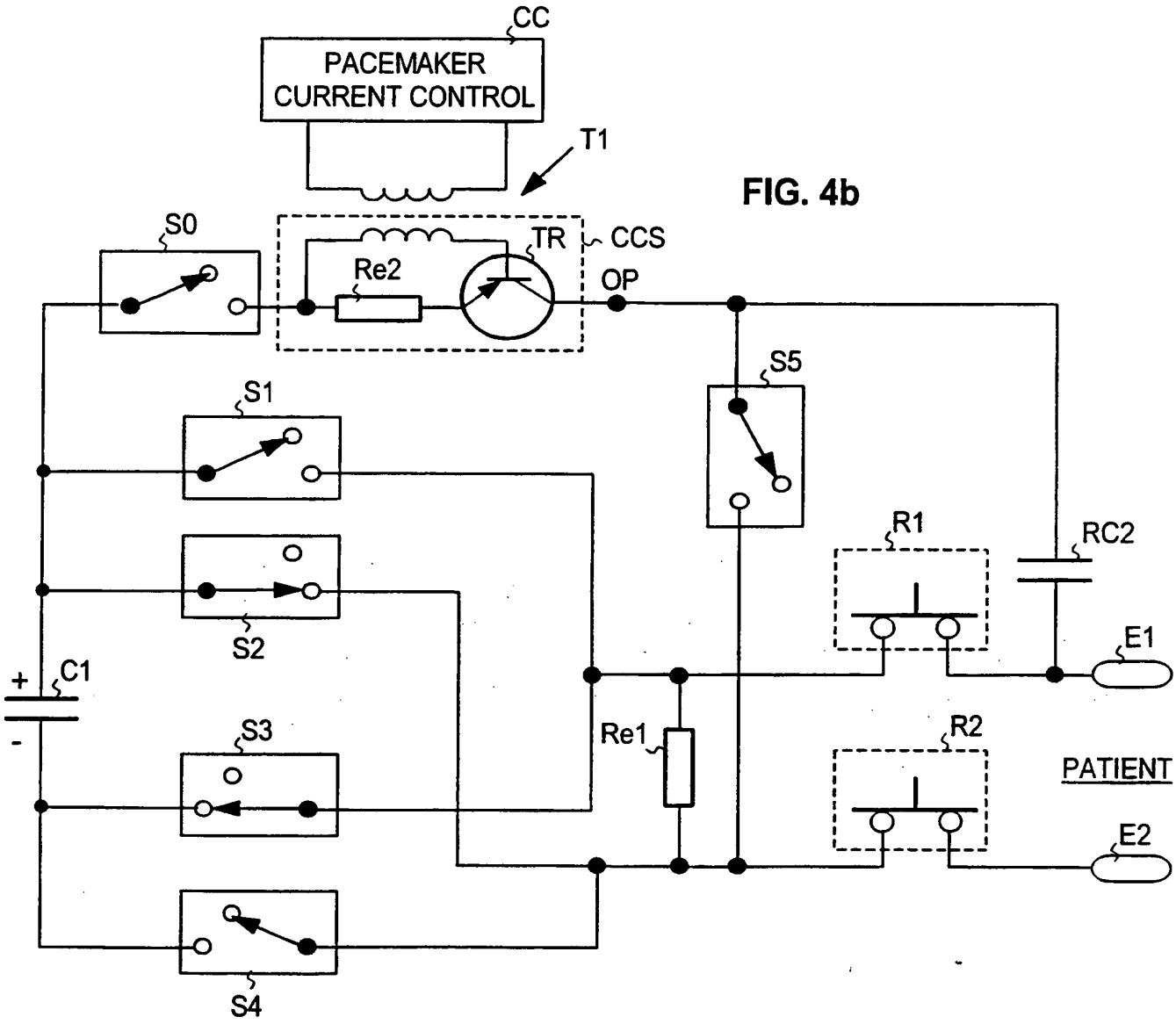

FIG. 4b

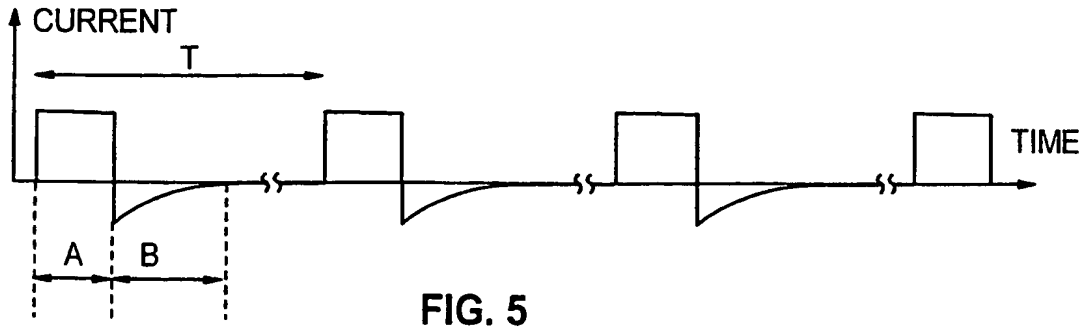

FIG. 5

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 00/00894

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/39, A61N 1/362
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 0021609 A1 (MEDTRONIC PHYSIO-CONTROL MANUFACTURING CORP.), 20 April 2000 (20.04.00), page 7, line 24 - page 8, line 18; page 15, line 9 - line 21, figure 4	12
A	WO 9839060 A1 (PHYSIO-CONTROL MANUFACTURING CORPORATION), 11 Sept 1998 (11.09.98), figure 1, abstract	1-16
A	US 4635639 A (D.T. HAKALA ET AL.), 13 January 1987 (13.01.87), abstract	1-16

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
11 January 2001	29-01-2001
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Nikolaj Hautaviita/AE Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

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INTERNATIONAL SEARCH REPORT

Information on patent family members

04/12/00

International application No.
PCT/FI 00/00894

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0021609 A1	20/04/00	NONE	
WO 9839060 A1	11/09/98	CN 1249695 T	05/04/00
		EP 0966312 A	29/12/99
		US 5824017 A	20/10/98
		US 6041254 A	21/03/00
US 4635639 A	13/01/87	NONE	

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